

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF SOUTH CAROLINA  
BEAUFORT DIVISION**

UNITED STATES OF AMERICA et al., EX REL.  
SCARLETT LUTZ and KAYLA WEBSTER,

*Plaintiffs/Relators,*

v.

LABORATORY CORPORATION OF  
AMERICA HOLDINGS,

*Defendant.*

CA No. 9:14-cv-3699-RMG

**DEFENDANT’S MOTION TO EXCLUDE TESTIMONY OF  
RELATORS’ EXPERT RAJA SEKARAN**

Defendant Laboratory Corporation of America Holdings (“LabCorp”) respectfully moves, pursuant to Federal Rules of Evidence 104(a), 401, 402, 403, 702, 703, to exclude the testimony of Raja Sekaran, a witness proffered as an expert by Relators Scarlett Lutz and Kayla Webster.

**I. INTRODUCTION**

Raja Sekaran is a lawyer who worked in the Government from 1997 to 2002. Since then, he has served as in-house counsel for two health care delivery systems and as a partner at a private law firm serving health care industry clients. His testimony does not constitute “expert” opinion and should be excluded for at least two reasons.

First, most of his opinions involve interpreting and applying statutes and regulations. For example, although regulations of the Inspector General of the Department of Health and Human Services (“OIG-HHS”) “ensure consideration” of requests for Special Fraud Alerts within a sixty-day period each year, Sekaran opines that the agency does not consider all such requests but merely “processe[s]” them. Solicitation of New Safe Harbors and Special Fraud Alerts, 77 Fed. Reg.

76434, 76434 (Dec. 28, 2012); Ex. A, Sekaran Tr. 193:13–194:8. But as this Court has explained, “[i]t is, of course, well settled, that it is the duty of the Court, and not a party’s expert, to state the meaning of the law,” *United States v. Berkeley Heartlab, Inc.*, No. 14-cv-00230, 2017 WL 2773794, at \*3 (D.S.C. June 26, 2017) (Gergel, J.) (citing *United States v. Barile*, 286 F.3d 749, 760 (4th Cir. 2002)). Sekaran’s testimony should be excluded because it intrudes upon the province of this Court.

Second, Sekaran’s opinions focus on his view of LabCorp’s state of mind and intention when it submitted its 2013 and 2014 fraud requests anonymously, which Sekaran testified was intended to minimize scrutiny of LabCorp’s own actions. This ignores that proceeding in such fashion is accepted industry practice, and that LabCorp had been cooperating with the government’s investigation for many months by the time it submitted its second request for a fraud alert. Indeed, Sekaran acknowledged such oversights during his deposition and agreed that portions of his expert report should be stricken. Regardless, Sekaran’s personal opinions on this topic are inadmissible because “conjecture” about “the intent, motives, or states of mind of corporations” has “no basis in any relevant body of knowledge or expertise.” *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (internal quotation marks omitted). Because Sekaran’s testimony does not draw upon any body of specialized knowledge, this Court should not allow him to testify as an expert.

## **II. BACKGROUND**

This litigation centers around “processing and handling” fees paid by HDL and Singulex from 2010 to 2014. These payments were improper under the Anti-Kickback Statute (“AKS”), and the Government successfully sued HDL, Singulex, HDL’s CEO Tonya Mallory, and the companies’ marketing firm BlueWave under the False Claims Act (“FCA”). Relators assert that LabCorp is liable for claims submitted by HDL and Singulex because doctors would sometimes

order tests from both LabCorp and HDL or Singulex for their patients, and sometimes, a LabCorp in-office phlebotomist (“IOP”) who was already drawing blood for the LabCorp test would also draw blood for the HDL or Singulex test as a courtesy to the patient, to spare the patient a second needle stick.

LabCorp submitted two requests for a “Special Fraud Alert” from OIG regarding processing and handling fees. Ex. B (2013 request); Ex. C (2014 request). LabCorp learned in mid-2012 that its IOPs might be sometimes drawing blood for HDL and Singulex tests for which doctors received P&H payments, but LabCorp did not submit the first request until February 2013 because the company had to solicit information from its various divisions, consult with counsel, and prepare the request—and also because the agency’s governing statute and regulations guarantee consideration and publication of requests submitted only during a single 60-day window each year. Ex. D, King 30(b)(6) Tr. 260:8–261:17; 42 U.S.C. § 1320a-7d(a)(1)(A); 77 Fed. Reg. at 76434. The request asked OIG to issue an alert clarifying whether such payments were improper and potential violations of the AKS. Ex. B. Following common practice in the industry, LabCorp submitted the request anonymously through counsel. Ex. E, King Tr. 282:20–283:13; Ex. F, Sorensen Report ¶ 28. Even so, the federal government soon issued to LabCorp a subpoena on November 4, 2013. Ex. G. LabCorp resubmitted its Special Fraud Alert request—fully aware that LabCorp had been cooperating with the government to respond to the subpoena—during the next 60-day window in February 2014. Ex. C. HHS-OIG issued the fraud alert on June 25, 2014, bringing HDL’s and Singulex’s processing and handling payments to a halt. Ex. H.

Relators have retained Raja Sekaran to offer expert testimony “regarding the processes available for healthcare providers and other market participants to disclose fraud and abuse [] concerns to the government.” Ex. I, Sekaran Report at 2. Sekaran worked at HHS-OIG from

January 1997 until September 2002, nearly twenty years ago. *Id.* Since then he has worked as an in-house lawyer for two health care delivery systems and as a partner in a private law firm representing health care clients. *Id.*

Among other things, Sekaran intends to testify about his understanding of the regulation stating that HHG-OIG will “ensure consideration” of Special Fraud Alerts submitted during an annual 60-day submission period. Ex. A, Sekaran Tr. 193:13–15; 77 Fed. Reg. at 76434. Moreover, Sekaran intends to testify that LabCorp submitted its fraud requests anonymously with an intent to “minimize[] the likelihood that HHS-OIG would scrutinize LabCorp’s own conduct in drawing blood for HDL tests.” Ex. I, Sekaran Rpt. ¶ 63.

### III. LEGAL STANDARD

Under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589–90 (1993), a witness cannot provide expert testimony without satisfying four conditions:

*First*, the expert must have “scientific, technical, or other specialized knowledge” that can “help the trier of fact to understand the evidence or to determine a fact in issue.” Fed. R. Evid. 702(a).

*Second*, the expert’s testimony must be “based on sufficient facts or data.” Fed. R. Evid. 702(b). Thus, “trial judges may evaluate the data offered to support an expert’s bottom-line opinions to determine if that data provides adequate support to mark the expert’s testimony as reliable.” *E.E.O.C. v. Freeman*, 778 F.3d 463, 472 (4th Cir. 2015) (Agee, J., concurring). The court may exclude an opinion if “there is simply too great an analytical gap between the data and the opinion proffered.” *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

*Third*, the expert’s testimony must be “the product of reliable principles and methods.” Fed. R. Evid. 702(c). Courts consider whether the “expert developed his opinions expressly for the purposes of testifying,” *Wehling v. Sandoz Pharms. Corp.*, 162 F.3d 1158 (4th Cir. 1998), or

“failed to meaningfully account for . . . literature at odds with [his] testimony,” *McEwen v. Balt. Wash. Med. Ctr. Inc.*, 404 F. App’x 789, 791–92 (4th Cir. 2010).

*Fourth*, the expert must have “reliably applied the principles and methods to the facts of the case.” Fed. R. Evid. 702(d). “This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid,” *Daubert*, 509 U.S. at 592–93, and whether the expert has “faithfully appl[ied] the methodology to facts,” *Roche v. Lincoln Prop. Co.*, 175 F. App’x 597, 602 (4th Cir. 2006).

As the proponents of Sekaran’s testimony, Relators must establish its admissibility by a preponderance of proof. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001). Because the Relators cannot do so, the Court should exclude Sekaran’s testimony.

#### **IV. ARGUMENT**

Sekaran’s testimony is inadmissible for at least two reasons. First, the testimony improperly infringes upon the province of the Court to determine the meaning of relevant law. Second, Sekaran improperly speculates about LabCorp’s state of mind.

##### **A. Sekaran purports to do the Court’s job by defining the meaning of the law.**

“It is, of course, well settled, that it is the duty of the Court, and not a party’s expert, to state the meaning of the law.” *Berkeley Heartlab, Inc.*, 2017 WL 2773794, at \*3. For that reason, “opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.” *United States v. McIver*, 470 F.3d 550, 561–62 (4th Cir. 2006). Because “[t]he only legal expert in a federal courtroom is the judge,” there cannot be expert testimony about what the law requires. *United States v. Caputo*, 517 F.3d 935, 942 (7th Cir. 2008).

Sekaran’s testimony attempts to do exactly that. His report purports to provide an “expert opinion regarding the processes available for healthcare providers and other market participants to disclose fraud and abuse [] concerns to the government.” Ex. I, Sekaran Rpt. at 2. But governing

statutes, regulations, and agency guidance are what determine the appropriate channels for reporting fraud and abuse—and “the meaning of [a] statute and regulations . . . [is] a subject for the court, not for testimonial experts.” *Caputo*, 517 F.3d at 942.

Because HDL’s and Singulex’s processing and handling fees did not reach LabCorp’s corporate radar until mid-2012, and because it took several months to solicit information and consult with counsel, LabCorp submitted its request for a fraud alert to OIG in the February 2013 submission period and then again in February 2014. Ex. B; Ex. C; Ex. D, King 30(b)(6) Tr. 260:8–261:17. LabCorp followed the law by requesting the fraud alert during these windows. The Health Insurance Portability and Accountability Act mandates that HHS-OIG accept proposals for special fraud alerts annually “during a 60-day period.” 42 U.S.C. §1320a-7d (a)(1)(A). OIG accordingly issued a solicitation of potential special fraud alerts on December 28, 2012, which required submissions “no later than 5 p.m. on February 26, 2013.” 77 Fed. Reg. at 76434. It issued a similar solicitation in 2014. Solicitation of New Safe Harbors and Special Fraud Alerts, 78 Fed. Reg. 78807, 78807 (Dec. 27, 2013).

LabCorp submitted its requests for a fraud alert during HHG-OIG’s submission period in February 2013 and February 2014 in part because the agency “ensure[s] consideration” of fraud alert requests submitted within the period. 77 Fed. Reg. at 76434. Sekaran, however, begs to differ: “I don’t think it ensures consideration.” Ex. A, Sekaran Tr. 193:1. There is no “guarantee of consideration.” *Id.* 193:13–15. According to Sekaran, all that is guaranteed is that the request will be “processed,” not considered. *Id.* 193:17–194:2.

If OIG “fails to follow its own procedures or regulations, [its] actions are generally invalid” and so Sekaran’s theory makes little sense. *Nader v. Blair*, 549 F.3d 953, 962 (4th Cir. 2008). But regardless, the Court (and not Sekaran) has the exclusive role of interpreting the agency’s

regulations and determining their legal effect. Allowing Sekaran to testify about the law would confuse jurors and provide no countervailing benefit. *See* Fed. R. Evid. 403.

Sekaran also testified that “LabCorp could have submitted a request to HHS-OIG for a Special Fraud Alert ‘at any time,’” because there was “no magic window.” Ex. I, Sekaran Report ¶ 60. Sekaran insisted that the sixty-day window was nothing more than the agency’s “preference” because “people want to manage their workload.” Ex. A, Sekaran Tr. 191:7, 191:13–14. To be sure, the Act elsewhere suggests that fraud alerts can be presented “at any time.” 42 U.S.C. §1320a-7d(c)(1)(A); Ex. I, Sekaran Report ¶ 28. But whether, as a legal matter, LabCorp could have requested a fraud alert at any time (under one subsection of the statute) or during the statutory 60-day period (under another subsection) is irrelevant for purposes of this motion.

The only issue is *who* decides that question: the Court or Sekaran? On this score, there is no doubt. Deciding whether an “interpretation of [a] statute is correct” is perhaps the most “familiar judicial exercise” of all. *Zivotofsky ex rel. Zivotofsky v. Clinton*, 566 U.S. 189, 196 (2012). To say what the law means has been “emphatically the province and duty of the judicial department” for centuries. *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803). Because there is no question for the jury on this issue, there is no place for Sekaran’s opinion.

Finally, Sekaran claims that LabCorp could have sought an advisory opinion, rather than a special fraud alert, that would have more effectively sounded the alarm on HDL and Singulex. Ex. A, Sekaran Tr. 140:5–8; Ex. I, Sekaran Report ¶¶ 29–35, 61–62. But agency guidance makes clear that OIG issues advisory opinions only regarding the requesting party’s “existing or proposed business arrangement.” OIG-HHS, Advisory Opinions FAQ, <https://oig.hhs.gov/faqs/advisory-opinions-faq.asp> (last visited Mar. 12, 2021). The guidance specifically notes that advisory opinions are “NOT appropriate” for “activities in which the party requesting the advisory opinion

is not, and does not plan to be, involved.” *Id.* For example, the agency “cannot issue an opinion to Company A about the business practice of Company B, unless Company A is a current or prospective party to Company B’s business practice.” *Id.* Because LabCorp never paid physicians P&H fees, nor considered doing so, LabCorp could not have sought an advisory opinion about the propriety of such fees.

Hardly deterred, Sekaran believes that “sophisticated providers like LabCorp” could just ignore OIG’s guidance and “hir[e] an inside-the-Beltway sophisticated law firm like Hogan Lovells” that would know well enough to disregard “the four corners of the FAQ.” Ex. A, Sekaran Tr. 145:15–148:24. And Sekaran is familiar with the work of Hogan Lovells because he knows “one or two current attorneys there” and because his “wife’s mentor was a lawyer” there. *Id.* 149:6–18. This baseless conjecture has no place in a courtroom—especially not when cited to support an expert’s improper interpretation of the law.

The governing statutes, regulations, and guidance determine whether LabCorp could have sought an advisory opinion. It is the Court’s responsibility to interpret that legal framework. Expert testimony has no say in the matter.

**B. Sekaran’s proposed testimony improperly speculates about LabCorp’s intent.**

In addition to interpreting statutes and regulations, Sekaran’s testimony also purports to read LabCorp’s corporate mind, providing yet another reason to exclude his testimony.

Rule 702’s requirement that an expert have “scientific, technical, or other specialized knowledge” “guards against the admission of subjective or speculative opinions.” *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 541 (S.D.N.Y. 2004). Opinions “on the intent, motives or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise”—as many courts have held. *Id.* at 546; *see, e.g., Knight v. Boehringer Ingelheim Pharms., Inc.*, 323 F. Supp. 3d 837, 852 (S.D. W. Va. 2018); *Wise v. C.R.*



*Bard, Inc.*, No. 12-cv-01378, 2015 WL 521202, at \*3–5 (S.D. W. Va. Feb. 7, 2015); *Yates v. Ford Motor Co.*, No. 12-cv-752, 2015 WL 3448905, at \*4–5 (E.D.N.C. May 29, 2015); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 721 (S.D. W. Va. 2014); *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 12-md-02327, 2014 WL 186872, at \*6 (S.D. W. Va. Jan. 15, 2014); *SMD Software, Inc. v. EMove, Inc.*, 945 F. Supp. 2d 628, 643 (E.D.N.C. 2013).

In short, “[i]nferences about the intent or motive of parties or others lie outside the bounds of expert testimony.” *In re Rezulin*, 309 F. Supp. at 547. Why a company acted the way it did is a “lay matter[] which a jury is capable of understanding and deciding without the expert’s help.” *Id.* at 546. For that reason, courts regularly exclude “‘expert’ testimony as to the ‘real motive’ behind certain business transactions.” *Id.*

Sekaran’s testimony flouts this fundamental rule. LabCorp submitted its fraud requests anonymously through counsel, which is an industry-accepted and prudent practice. Ex. E, King Tr. 282:20–283:13; Ex. F, Sorenson Report ¶ 28. Yet, Sekaran speculates that LabCorp submitted its requests anonymously to “minimize[] the likelihood that HHG-OIG would scrutinize LabCorp’s own conduct in drawing blood for HDL tests.” Ex. I, Sekaran Report ¶ 63. In his deposition, Sekaran claimed it “self-evident” that LabCorp “did not want the scrutiny.” Ex. A, Sekaran Tr. 211:16–18.

Sekaran’s speculation ignores that LabCorp resubmitted its anonymous request for a fraud alert in February 2014, when LabCorp was already cooperating with the government’s investigation. Plainly, LabCorp’s submissions were not driven by an intent to stay off the government’s radar. Sekaran’s response? “[T]he point, I think, in resubmitting the exact same one was to try to get some credit points from the government so to speak, that look, we had done

this.” Ex. A, Sekaran Tr. 233:9–12. This is groundless speculation, not the product of “scientific, technical, or other specialized knowledge,” as Rule 702 requires.

Other examples of Sekaran’s speculation abound. LabCorp CEO Dave King supposedly wanted “to claim credit that he notified the government” but did not want “anything to come out too quickly.” Ex. A, Sekaran Tr. 176:19–22. LabCorp’s fraud requests were purportedly on “a slow boat.” *Id.* 176:19. This was all apparently done by LabCorp to “get some credit should it be needed later on . . . but not too much credit.” *Id.* 235:8–11. “They didn’t want to go too far.” *Id.* 235:13. And so forth. None of Sekaran’s speculation on LabCorp’s state of mind has any support in the record. His conclusions are nothing more than personal beliefs dressed in the guise of expert testimony.

Sekaran’s speculation is not helpful and intrudes on the province of the trier of fact. This Court should not countenance Sekaran taking the stand and claiming that his experience as a health care lawyer gives him special clairvoyance regarding LabCorp’s motivations. Such testimony relies upon mere “belief” and “speculation,” not “scientific, technical, or other specialized knowledge,” and therefore should be excluded. *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999) (emphasis in original).

## V. CONCLUSION

LabCorp respectfully asks the Court to grant this motion and exclude the testimony of Raja Sekaran.

Dated: March 12, 2021

Respectfully submitted,

*s/ James Lynn Werner*

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**CERTIFICATE OF SERVICE**

I certify that on March 12, 2021, I electronically filed the foregoing DEFENDANT’S MOTION TO EXCLUDE TESTIMONY OF RELATORS’ EXPERT RAJA SEKARAN using the CM/ECF system, which will send notification of this filing to all counsel of record.

*s/ James Lynn Werner*  
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